

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

#### REMARKS

This Amendment is responsive to the Office Action dated August 10, 2007. Applicant has canceled claims 10 and 32, amended claims 1, 11, 29 and 33, and added new claims 35 and 36. Claims 1-9, 11-31, and 33-36 are pending upon entry of this amendment.

#### Amendment To The Specification

Applicant has amended the specification to identify that the application is a continuation of U.S. Patent Application No. 09/963,149, filed on September 25, 2001, which claims the benefit of U.S. provisional application number 60/235,660, filed September 26, 2000. Applicant previously requested the amendment in item 2 of the Continuation Patent Application Transmittal form filed February 19, 2004. Applicant believes that the amendment in the Transmittal was entered. To ensure entry, however, Applicant hereby submits substantially the same amendment in this Amendment.

#### Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-5, 7-10 and 29-34 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,690,691). Applicant respectfully traverses the rejection. Chen et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 1, as amended, recites a system for gastric stimulation of a patient comprising a plurality of sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient; an implantable gastric stimulator coupled to the plurality of sensing electrodes, and a plurality of stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient. Per claim 1, the implantable gastric stimulator receives the sensed intrinsic gastric activity and performs an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determines whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal. The electrical stimulation disrupts the normal gastric activity of the stomach, as recited in claim 1.

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

The Office Action stated that, with regard to claims 1-3 and 5, Chen discloses a gastric pacemaker comprising a plurality of sensing electrodes, a plurality of stimulation electrodes contained in leads for coupling, and an implantable gastric stimulator. The Office Action further stated that Chen discloses that the electrodes are positioned at different locations of the stomach wall, and are controlled by an electronic controller that is programmable. The Office Action also stated that Chen further discloses that the controller can be programmed to enhance or accelerate normal peristaltic movement and to attenuate peristaltic movement to treat eating disorders. On this basis, the Office Action concluded that Chen anticipates claims 1-3 and 5. Applicant respectfully disagrees.

In contrast to the features recited by claim 1, Chen fails to teach or disclose a plurality of sense electrodes for sensing intrinsic gastric activity from the stomach wall of the patient, in combination with an implantable gastric stimulator that receives the sensed intrinsic gastric activity and performs an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determines whether to create an electrical stimulation based at least in part upon the classification. Instead, Chen discloses sense electrodes that are employed after electrical stimulation has been applied to sense the strength of contraction(s) that are evoked in response to the electrical stimulation.<sup>1</sup>

The stimulator described by Chen does not analyze sensed intrinsic gastric activity to determine whether to create an electrical stimulation. Instead, as stated above, the Chen stimulator analyzes sensed signals that are not intrinsic, but generated in response to delivery of electrical stimulation. In Chen, the parameters of the initial electrical stimulation are adjusted if the sensed strength of a contraction produced in response to electrical stimulation is too weak or too strong.<sup>2</sup> As such, the device in Chen clearly does not sense intrinsic gastric activity from the stomach wall of the patient as recited by independent claim 1. Rather, the sensors in Chen sense the contractions induced by the applied electrical stimulation. This is an example of a fundamental difference that distinguishes the claimed invention from the Chen reference.

In addition, Chen fails to teach or disclose electrical stimulation that disrupts the normal gastric activity of the stomach. To the contrary, Chen teaches phased, multipoint electrical

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<sup>1</sup> *Chen et al.*, col. 3, lines 50-54.

<sup>2</sup> *Id.* at col. 3, lines 55-57.

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

stimulation to pace peristaltic movement of material through the GI tract. Moreover, Chen does not teach the disruption of normal gastric activity as recited by claim 1. Instead, Chen focuses on phased pacing to treat disorders of the GI tract where peristaltic flow has slowed or stopped (e.g., gastroparesis in the stomach; constipation in the colon, etc.)<sup>3</sup> or retrograde, phased pacing to treat disorders where peristaltic flow is too fast.<sup>4</sup> As such, Chen fails to disclose the disruption of normal gastric activity but rather focuses on phased stimulation to treat GI tract disorders, i.e., instances of abnormal gastric activity.

Further, as shown in FIG. 3 of Chen, the stimulation delivered by the three electrodes phased relative to one another is paced to stimulate the stomach at 3 cycles per minute (cpm).<sup>5</sup> Chen also states that "in the normal human stomach, the gastric slow wave is approximately 3 cpm."<sup>6</sup> Accordingly, Chen appears to teach paced stimulation at a rate corresponding to normal gastric activity for patients having GI tract disorders that cause abnormal gastric activity.

The Office Action indicated that Chen discloses a controller that "can be programmed to enhance or accelerate normal peristaltic movement and further that can attenuate peristaltic movement to treat eating disorders (Abstract)"<sup>7</sup> (Emphasis added). Applicant respectfully asserts that, in the case of attenuation, the Chen abstract fails to characterize the peristaltic movement as "normal," as stated in the above Office Action passage.

Instead, the relevant portion of the Chen abstract simply states that the gastric pacemaker "can be programmed with parameters to enhance or accelerate peristaltic movement through the gastric tract or to attenuate the peristaltic movement to treat such conditions eating disorder or diarrhea [*sic*]."<sup>8</sup> As stated above, Chen teaches the treatment of GI tract disorders and not delivery of stimulation to disrupt normal gastric activity of the stomach, as required by claim 1.

In the Response to Arguments section, the Office Action stated that "Chen further discloses that it contains an electronic controller that senses intrinsic activity of the stomach," and that the "claims never limit the sensing to exclude response sensing." First, Chen does not describe sensing of intrinsic activity. Second, although the claims do not exclude response

<sup>3</sup> *Id.* at col. 6, lines 48-50.

<sup>4</sup> *Id.* at col. 6, lines 61-63.

<sup>5</sup> *Id.* at col. 7, lines

<sup>6</sup> *Id.* at col. 6, lines 43 and 44.

<sup>7</sup> Section 6, paragraph 2 of the Office Action mailed August 10, 2007

<sup>8</sup> *Chen et al.*, Abstract

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

sensing, they require sensing of intrinsic activity and, more particularly, analysis of such intrinsic gastric activity to classify the activity as normal or abnormal, and determination of whether to create an electrical stimulation based at least in part upon the classification. Moreover, the electrical stimulation disrupts the normal gastric activity of the stomach. Accordingly, the question is not what claim 1 excludes, but what it requires. Chen plainly lacks any teaching of the analysis of intrinsic gastric activity and a determination of whether to create an electrical stimulation based at least in part upon the classification of such activity as normal or abnormal. Instead, Chen describes sensing gastric activity that is not intrinsic, but rather evoked in response to application of electrical stimulation.

Consistent with the analysis of evoked gastric activity, the Office Action notes that Chen "discloses that the sensed waveforms of the stomach are used to determine the correct stimulation pattern." In the passage cited by the Office Action<sup>9</sup>, Chen describes closed loop feedback to sense the strength of contractions in response to electrical stimulation, and adjust stimulation parameters to achieve a desired response. Hence, there is no mention in Chen of analyzing intrinsic gastric activity and determining whether to create an electrical stimulation based at least in part upon the analysis, as set forth in the claims.

Chen clearly fails to teach or disclose that the stimulator performs an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determines whether to create an electrical stimulation based at least in part upon the classification. Chen makes no mention of such a classification, nor any reason to make such a classification. A similar feature was previously recited in canceled claim 10. With respect to claim 10, however, the Office Action did not appear to address these features. Furthermore, as stated before, the sensing electrodes in Chen sense contractions and their respective strength in response to electrical stimulation. As such, Chen clearly fails to teach or disclose the sensing of intrinsic activity, much less the classification of such activity as normal or abnormal.

For at least these reasons, Chen fails to teach or disclose all feature of claim 1. Thus, independent claim 1 and corresponding dependent claims 2-5 and 7-9 are not anticipated by Chen.

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<sup>9</sup> Col. 5, lines 55-60.

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

Additionally, with respect to the various dependent claims, Chen fails to disclose the claimed invention. With respect to claim 7, for example, Chen fails to disclose that the sensing electrodes communicate the sensed intrinsic gastric activity to the implantable gastric stimulator for identifying at the implantable gastric stimulator an interval, an amplitude, and a duration of the sensed intrinsic gastric activity. The Office Action stated that Chen, at column 5, lines 49-51 and 55-63, discloses that the sensing electrodes communicate with the stimulator identifying the frequency, strength and timing of the intrinsic electric activity. To the contrary, the passages cited by the Office Action describe the adjustment of the pulse amplitude and duration of the applied stimulation, i.e., stimulation parameters, based on the sensed strength of the contraction resulting from the prior electrical stimulation. There is no mention in Chen of identifying interval, amplitude and duration of sensed intrinsic gastric activity. Thus, Chen fails to teach or disclose the features of claim 7.

With respect to claim 8, Chen fails to teach or disclose that the sensing electrodes communicate the sensed intrinsic gastric activity to the implantable gastric stimulator for identifying at the implantable gastric stimulator a frequency spectrum of the sensed intrinsic gastric activity. Again, Chen describes the sensor electrodes as sensing contractions that are evoked in response to stimulation to determine the contraction strength, and thereby determine adjustments to the stimulation. Chen fails to disclose the communication of sensed intrinsic gastric activity to an implantable gastric stimulator for identifying at the stimulator a frequency spectrum of the sensed intrinsic gastric activity, as required by claim 8. The Office Action did not seem to address this limitation specifically.

With respect to claim 9, Chen fails to teach or disclose that the stimulator analyzes sensed intrinsic gastric activity and classifies the sensed intrinsic gastric activity as slow wave or peristaltic wave. The Office Action stated that Chen, at column 6, lines 43-53, discloses that the stimulator looks at the activity to see if it is a slow wave or a peristaltic wave and, based on this, stimulates the organ. However, the cited passage generally states that the gastric slow wave in the normal human stomach is approximately 3 cpm and that the invention contemplates treating disorders where peristaltic flow has slowed or stopped (e.g., gastroparesis in the stomach; constipation in the colon, etc.) by pacing the organ with electrical stimulations that have a frequency equal to or greater than the natural frequency. Contrary to the assertion in the Office

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

Action, Chen makes no mention of analysis of sensed intrinsic gastric activity, much less the classification of sensed intrinsic gastric activity as a slow wave or peristaltic wave.

For at least these additional reasons, Chen fails to teach or disclose all features of independent claim 1 and corresponding dependent claims 2-5 and 7-9. Accordingly, Chen fails to anticipate claims 1-5 and 7-9.

Independent claim 29, as amended, recites a method for gastric stimulation of a patient comprising sensing the intrinsic gastric activity on the stomach wall of a patient, classifying the sensed activity as normal or abnormal, determining when to apply electrical stimulation to the stomach walls of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal, and disrupting normal gastric activity of the stomach with the electrical signal.

With respect to claims 29 and 31-34, the Office Action stated that Chen discloses a method for gastric stimulation comprising sensing the activity, determining the activity and when to apply the stimulation and then stimulating to disrupt normal gastric activity. On this basis, the Office Action concluded that Chen anticipates claims 29 and 31-34. Applicant respectfully disagrees.

Substantially the same deficiencies in Chen identified with respect to independent claim 1 apply to independent claim 29. For instance, Chen fails to teach or disclose sensing the intrinsic gastric activity on the stomach wall of a patient. Instead, Chen teaches that the sensor electrodes sense contractions that are evoked in response to applied electrical stimulation. Additionally, Chen fails to teach or disclose disrupting normal gastric activity of the stomach with the electrical signal, much less classifying the sensed activity as normal or abnormal, and disrupting normal gastric activity with an electrical signal that is formed in response to determining when to apply electrical stimulation to the stomach walls of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, as set forth in amended claim 29. Rather, Chen teaches electrical stimulation to treat disorders of the GI tract, i.e., treat abnormal gastric activity to restore normal gastric activity.

Chen simply provides no teaching that would have suggested classifying the sensed intrinsic electrical gastric activity as normal or abnormal, determining when to apply electrical

Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

stimulation to the stomach walls of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, and forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal, as set forth in claim 29. With respect to canceled claim 32, the Office Action failed to address where Chen discloses a similar feature. Furthermore, as stated before, the sensing electrodes in Chen sense contractions and their respective strength in response to electrical stimulation. As such, Chen fails to teach or disclose the sensing of intrinsic activity, much less the classification of such activity as normal or abnormal.

For at least these reasons, Chen fails to teach or disclose all feature of claim 29. Thus, independent claim 29 and corresponding dependent claims 31-34 are not anticipated by Chen.

Additionally, with respect to the various dependent claims, Chen fails to teach or disclose the claimed invention. With respect to claim 31, for example, Chen fails to teach or disclose the method of claim 29, further comprising analyzing the sensed intrinsic gastric activity and classifying the sensed intrinsic gastric activity as slow wave or peristaltic wave. Substantially the same deficiencies identified above with respect to claim 9 apply to claim 31.

With respect to claim 33, Chen fails to teach or disclose that the step of determining a percentage of normal events and the step of disrupting applies the electrical signal for the percentage of electrical events. Moreover, the Office Action failed to address such a feature.

With respect to claim 34, Chen fails to teach or disclose that the step of disrupting is triggered by electrical activity classified as normal. Further, the Office Action failed to address such a feature.

For at least these additional reasons, Chen fails to teach or disclose all features of independent claim 29 and corresponding dependent claims 30-34. Accordingly, Chen fails to anticipate claims 29-31, 33 and 34.

Chen et al. fails to disclose each and every limitation set forth in claims 1-5, 7-10 and 29-31, 33 and 34. For at least these reasons, the Office Action failed to establish a prima facie case for anticipation of Applicant's claims 1-5, 7-10 and 29-31, 33 and 34 under 35 U.S.C. 102(b). Withdrawal of this rejection respectfully requested.

Application Number 10/782,087

Response to Office Action mailed August 10, 2007

**Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 6, 11-27 and 30 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. as applied to claims 1 and 7 above, and further in view of Gordon (US 6,895,278). The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 6 and 11-27 are dependent on independent claim 1. Claim 30 is dependent on independent claim 29. Accordingly, each dependent claim includes all features of the respective independent claim. All deficiencies identified with respect to the respective independent claims also apply to dependent claims 6, 11-27 and 30. Furthermore, the Gordon reference fails to overcome the identified deficiencies.

Additionally, with respect to the various dependent claims, Chen and Gordon fail to teach or disclose the claimed invention. With respect to claim 12, as one example, Chen and Gordon fail to teach or disclose that the delivery of electrical stimulation is triggered by electrical activity classified as a plurality of normal events. As stated before, Chen fails to teach the classification of electrical activity as normal, much less the triggering of stimulation by the classification of electrical activity as a plurality of normal events.

With respect to claims 14-17, as further examples, Chen and Gordon fail to teach or suggest that the electrical stimulation is: delivered across the sensed intrinsic gastric activity; delivered with a spatial offset to the sensed intrinsic gastric activity; delivered with a temporal offset to the sensed intrinsic gastric activity; or delivered in anticipation of the next normal electrical activity, respectively. Furthermore, Gordon fails to overcome such deficiencies.

The Examiner also rejected claim 28 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. in view of Gordon as applied to claim 27 above, and further in view of Wernicke (US 5,188,104). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 28 is dependent on independent claim 1 and, therefore, contains all limitations of claim 1. All deficiencies identified with respect to the respective independent claims also apply



Application Number 10/782,087  
Response to Office Action mailed August 10, 2007

to the dependent claims. Furthermore, the Gordon and Wernicke references fail to overcome the identified deficiencies.

In view of the basic deficiencies discussed above, Applicants reserve further comment concerning the Chen, Gordon and Wernicke references. In so doing, however, Applicants neither admit nor acquiesce in the propriety of any aspect of the rejections or the Examiner's interpretation of the references or the limitations set forth in the claims.

For at least these reasons, the Office Action failed to establish a prima facie case for non-patentability of Applicant's claims 6, 11-28 and 30 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

#### **New Claims:**

Applicant has added claims 35 and 36 to the pending application. No new matter has been added by the new claims. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

As one example, the references fail to disclose or suggest a system comprising a plurality of sensing electrodes for sensing intrinsic electrical gastric activity from a stomach wall of a patient; an implantable gastric stimulator coupled to the sensing electrodes, wherein the implantable gastric stimulator receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, and wherein the stimulator creates electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal; and a plurality of stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient, the electrical stimulation being configured to disrupt normal gastric activity of the stomach, as required by claim 35.

As another example, the reference fail to disclose or suggest a method comprising sensing intrinsic electrical gastric activity from a stomach wall of a patient; classifying the intrinsic electrical gastric activity as normal or abnormal; applying electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach; and withholding

Application Number 10/782,087

Response to Office Action mailed August 10, 2007

application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal, as recited by claim 36.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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12-10-07

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